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10/594,674	02/13/2007	Mohammad Djavad Mossalayi	3665-223	2319

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ARLINGTON, VA 22203

EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,674

Applicant(s)

MOSSALAYI ET AL.

Examiner

PHUONG HUYNH

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 58-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 58, 61-63, 65 and 66 is/are rejected.
- 7) ☒ Claim(s) 59, 60 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 14 and 58-66 are pending and being acted upon in this Office Action.

Rejections Withdrawn

Applicant's arguments, see 6-7 of amendment, filed January 27, 2011, with respect to the rejection of claim(s) 14 and 40 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the claim amendment.

Because of the claims amendment and the DE19749277 A1 is no longer cited as prior art, it follows that the rejection of claims 14 and 61-63 under 35 U.S.C. 103(a) as being unpatentable over DE19749277 A1 (published May 5, 1999; PTO 1449) in view of US Pat No 5,028,592 (of record, issued July 2, 1991; PTO 892) has been withdrawn.

Likewise, the rejection of claims 14 and 58 under 35 U.S.C. 103(a) as being unpatentable over DE19749277 A1 (of record, published May 5, 1999; PTO 1449) in view of Heck et al (of record, Proc Natl Acad Sci 93:4036-4039, April 1996; PTO 892) has been withdrawn.

The new matter rejection of claim 40 under 35 U.S.C. 112, first paragraph has been withdrawn in view of cancellation of said claim in amendment filed January 27, 2011.

The following new ground of rejection is necessitated by the amendment filed January 27, 2011.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Jouault et al (of record, Glycobiology 11(8): 693-701, 2001; PTO 1449).

Jouault et al teach a pharmaceutical composition comprising at least one peptide such as FHENWPS, which is identical to the claimed SEQ ID NO: 1 and dissolved in a pharmaceutical acceptable carrier such as water (see page 699, left col., antigen recognition of synthesized phage-peptide, in particular). Given the reference peptide FHENWPS has the same structure as that claimed peptide of SEQ ID NO: 1; the reference peptide inherently binds to CD23 at least about 10^{-6} M. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure or sequence, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, the reference teachings anticipate the claimed invention.

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by US 20060233805 (claimed earliest priority to September 20, 2002; PTO 892).

US 20060233805 teaches a pharmaceutical composition comprising at least one peptide such as FHENWPS, which is identical to the claimed SEQ ID NO: 1, as an active compound (See claims 9 and 32 of the reference, paragraph 0085, 0055, 0051, in particular) and a pharmaceutical acceptable carrier known in the art (see paragraph 0051, in particular). Because the peptide is administered as a pharmaceutical composition, the reference peptide must dissolve in a pharmaceutical acceptable carrier in order to inject or administer to the subject. Given the reference peptide FHENWPS has the same structure as that claimed peptide of SEQ ID NO: 1; the reference peptide inherently binds to CD23 at least

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about 10⁻⁶ M. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure or sequence, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, the reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jouault et al (of record, Glycobiology 11(8): 693-701, 2001; PTO 1449) or US 20060233805 application (claimed earliest priority to September 20, 2002; PTO 892) each in view of US Pat No 5,028,592 (of record, issued July 2, 1991; PTO 892).

The teachings of Jouault et al or US 20060233805 application have been discussed supra. Jouault et al further teaches the peptide is useful for making antibody (see page 697, right col., in particular).

The invention in claims 60 and 61 differs from the teachings of the references only in that the peptide wherein the N-terminus is acylated.

The invention in claims 60 and 62 differs from the teachings of the references only in that the peptide wherein the N-terminus is acetylated.

The invention in claims 60 and 63 differs from the teachings of the references only in that the peptide wherein the C-terminus is amidated.

The '592 patent teaches protective groups such as acyl or acetyl group bound to the amino terminus or the amidated group to the C-terminus of any bioactive peptide to reduce the susceptibility of the peptide to acid or enzymatic hydrolysis (see col. 4, lines 50-66, in particular). The '592 patent teaches protected peptides are more pharmacologically active than the unprotected peptide (see col. 4, lines 65-66, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a protective group such as acyl or acetyl group bound to the amino terminus of a peptide and/or the amidated group to the C-terminus of any peptide as taught by the '592 patent to the peptide consisting of the amino acid sequence FHENWPS as taught by the Jouault et al or the US 20060233805 application.

One having ordinary skill in the art would have been motivated to do so because the protective groups would reduce susceptibility of the peptide to acid or enzymatic hydrolysis and as such, the protected peptide is more pharmacologically active than the unprotected peptide as taught by the '592 patent (see col. 4, lines 50-66, in particular).

Given the examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in *KSR International Co. V. Teleflex Inc.* 82 USPQ2d 1385 (2007) and the

Examination Guidelines set forth in the Federal Register (Vol. 72, No. 195, October 10, 2007) and incorporated recently into the MPEP (Revision 6, September 2007), the following rationales to support rejection under 35 U.S.C. 103(a) are noted:

- A) Combining prior art elements according known methods to yield predictable results.
- B) Use of known technique to improve similar products in the same way.
- C) "Obvious to try" --- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.
- D) Some teachings, suggestion, or motivation in the prior art that would lead to one of ordinary skill to modify the prior art reference to arrive at the claimed invention.

Since reducing enzymatic hydrolysis or peptide *in vivo* is desirable and have been predictable at the time the invention was made, there would have been reasonable expectation of success in combine the references teachings to arrive at the claimed invention. Obviousness is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR International Co. V. Teleflex Inc.* 82 USPQ2d 1385 (2007). From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Claims 14 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jouault et al (of record, *Glycobiology* 11(8): 693-701, 2001; PTO 1449) or US 20060233805 application (claimed earliest priority to September 20, 2002; PTO 892) each in view of Heck et al (of record, *Proc Natl Acad Sci* 93:4036-4039, April 1996; PTO 892).

The teachings of Jouault et al or US 20060233805 application have been discussed *supra*. Jouault et al further teaches the peptide is useful for making antibody (see page 697, right col., in particular).

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The invention in claim 58 differs from the teachings of the references only in that the peptide has at least one amino acid which is a D-isomer instead of naturally occurring L-isomer.

Heck et al teach in recent years, a growing number of synthetic peptides containing D-amino acids to capitalize on the residues' ability to provide improved protease stability (pharmacokinetic profile) of the bioactive peptides (see page 4039, col. 2, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to improve the stability of the peptide of Jouault et al or the US 2006023305 application by substituting the natural occurring L-amino acids in the peptide for the D-amino acid isomer as taught by Heck et al.

One having ordinary skill in the art would have been motivated to do so because Heck et al teach it is conventional at the time the invention was made to improve stability of the peptide by substituting any naturally occurring L-amino acid for any D-amino acid isomers to improve protease resistance, thereby improve the pharmacokinetic profile of the peptide, alter tertiary structure and affect activity of the bioactive peptides (see page 4039, col. 2, in particular).

Claim rejections under - 35 U.S.C. 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is New Matter.**

The recitation of “at least about” in new claim 66 has no support in the specification and the claims as originally filed. The specification discloses the peptide has a specific binding activity to CD23 of less than 10^{-6} kd or between 10^{-6} and 11^{-11} M, see page 13, lines 10-13. The term “at least about” broaden the Kd value to such as greater than 10^{-6} Kd.

The specification and the claims as originally do not support the limitation “comprised between at least about 10^{-6} and 11^{-11} M” as now claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The “= less than” in claim 66 is vague and indefinite because it is unclear if the phrase “= less than” means less than 10^{-6} M or “ $\leq 10^{-6}$ M”. The specification does not provide a standard for ascertaining the requisite “= less than”, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is suggested that claim 65 be amended to recite “...Kd equal less than 10^{-6} M” or “Kd is less than 10^{-6} M” since the specification does not disclose Kd is less than or equal to 10^{-6} M.

Claim Objection

Claim 59 is objected to because of the typographical error “NH2Gallyl-[NWG[allyl-]” Should have been “NH2G[allyl-] N W G[allyl-]”.

Claims 60 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The IFW official Fax number is (571) 273-8300.

Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Phuong Huynh/

Primary Examiner, Art Unit 1644